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| APPLICATION NO.   | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|-------------|----------------------|---------------------|------------------|
| 10/721,404  | 11/25/2003  | Takuya Tamatani      | 14539-004012        | 1646             |
| 26161   | 7590        | 04/14/2006           | EXAMINER            |                  |
| FISH & RICHARDSON PC<br>P.O. BOX 1022<br>MINNEAPOLIS, MN 55440-1022 |             |                      | OUSPENSKI, ILIA I   |                  |
|   |             |                      | ART UNIT            | PAPER NUMBER     |
|   |             |                      | 1644                |                  |

DATE MAILED: 04/14/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

|                              |                               |                                 |  |
|------------------------------|-------------------------------|---------------------------------|--|
| <b>Office Action Summary</b> | Application No.<br>10/721,404 | Applicant(s)<br>TAMATANI ET AL. |  |
|                              | Examiner<br>ILIA OUSPENSKI    | Art Unit<br>1644                |  |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 07 September 2005.
- 2a) ☐ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-25 and 27-69 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-25 and 27-69 are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### DETAILED ACTION

1. Applicant's Preliminary Amendment, filed 09/07/2005, is acknowledged.

Claim 26 has been canceled.

Claim 18 has been amended.

*Claims 1 – 25 and 27 – 69 are pending.*

2. The instant application appears to be in sequence compliance for patent applications containing nucleotide sequence and/or amino acid sequence disclosures.

3. For restriction purposes the following is noted:

The instant claims contain recitations of multiple types of JTT-1-regulating substances. These molecules are patentably distinct because their structures, physicochemical properties and/or mode of action are different, and they do not share a common structure that is disclosed to be essential for common utility. Therefore, the restriction has been set forth for each as separate groups, irrespective of the format of the claims.

The instant claims contain recitations of "regulating" the function of a JTT-1 antigen, thus encompassing methods of upregulating as well as downregulating said function. These methods are mutually exclusive in that they reach opposing endpoints, and in that they employ structurally distinct "agents" to accomplish these mutually exclusive endpoints. Consequently, the restriction has been set forth for methods relating to downregulation, and for methods relating to upregulation, as separate groups, irrespective of the format of the claims.

The instant claims contain recitations of various diseases or disorders. These pathological conditions are distinct because they differ in etiologies and therapeutic endpoints; thus each condition represents patentably distinct subject matter. Therefore, the restriction has been set forth for each as separate groups, irrespective of the format of the claims.

It is also noted that the instant claims contain generic recitations, e.g. of "low molecular weight compounds." In the event specific types of "low molecular weight compounds," or other specific types of generically recited compounds, are introduced into the claims during prosecution, additional restriction and/or species election may be required.

#### ***Restriction Requirement***

4. Restriction to one of the following inventions is required under 35 U.S.C. § 121:

I. Claims 1 – 2, 5 – 6, 9 – 14, and 16 – 17, drawn to a pharmaceutical composition comprising a drug that activates or stimulates the function of a JTT-1 antigen, wherein the drug is a low molecule weight compound, classified in Class 514, subclass 1.

II. Claims 1, 3, 5, 9, 11 – 13, and 16, drawn to a pharmaceutical composition comprising a drug that activates or stimulates the function of a JTT-1 antigen, wherein the drug is an antisense substance, classified in Class 514, subclass 44.

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III. Claims 1, 4 – 5, 9, 11 – 13, and 16, drawn to a pharmaceutical composition comprising a drug that activates or stimulates the function of a JTT-1 antigen, wherein the drug is a polypeptide, classified in Class 514, subclass 2.

IV. Claims 1 – 2, and 7 – 17, drawn to a pharmaceutical composition comprising a drug that inhibits or suppresses the function of a JTT-1 antigen, wherein the drug is a low molecule weight compound, classified in Class 514, subclass 1.

V. Claims 1, 3, 7, 9, 11 – 13, and 15 – 16, drawn to a pharmaceutical composition comprising a drug that inhibits or suppresses the function of a JTT-1 antigen, wherein the drug is an antisense substance, classified in Class 514, subclass 44.

VI. Claims 1, 4, 7, 9, 11 – 13, and 15 – 16, drawn to a pharmaceutical composition comprising a drug that inhibits or suppresses the function of a JTT-1 antigen, wherein the drug is a polypeptide, classified in Class 514, subclass 2.

VII – XII. Claims 18 – 37, drawn to a method treating an autoimmune disease by administering a pharmaceutical composition of one of Groups I - VI, classified in Class 514, subclass 1, for example.

XIII – XVIII. Claims 18 – 37, drawn to a method treating an allergic disease by administering a pharmaceutical composition of one of Groups I - VI, classified in Class 514, subclass 1, for example.

XIX – XXIV. Claims 18 – 37, drawn to a method treating an inflammatory disease by administering a pharmaceutical composition of one of Groups I - VI, classified in Class 514, subclass 1, for example.

XXV. Claims 38 – 39 and 43 – 52, drawn to a method of identifying a substance that regulates JTT-1 antigen function, comprising administering a test substance to a mouse transgenic for JTT-1, wherein the test substance is a low molecular weight compound, classified in Class 514, subclass 1.

XXVI. Claims 38, 40, 43, 45, 47 – 48, and 51, drawn to a method of identifying a substance that regulates JTT-1 antigen function, comprising administering a test substance to a mouse transgenic for JTT-1, wherein the test substance is an antisense substance, classified in Class 514, subclass 44.

XXVII. Claims 38, 41, 43, 45, 47 – 48, and 51, drawn to a method of identifying a substance that regulates JTT-1 antigen function, comprising administering a test substance to a mouse transgenic for JTT-1, wherein the test substance is a polypeptide, classified in Class 514, subclass 2.

XXVIII. Claims 38, 42, 43, 45, 47 – 48, and 51, drawn to a method of identifying a substance that regulates JTT-1 antigen function, comprising administering a test substance to a mouse transgenic for JTT-1, wherein the test substance is an antibody, classified in Class 424, subclass 130.1.

XXIX. Claims 53 – 57 and 60 – 69, drawn to a method of identifying a substance that regulates JTT-1 antigen function, comprising contacting a polypeptide comprising the extracellular domain of JTT-1 with a test substance, wherein the test substance is a low molecular weight compound, classified in Class 435, subclass 7.1.

XXX. Claims 53 – 56, 58, 60, 62, 64 – 65, and 67 – 68, drawn to a method of identifying a substance that regulates JTT-1 antigen function, comprising contacting a polypeptide comprising the extracellular domain of JTT-1 with a test substance, wherein the test substance is a polypeptide, classified in Class 435, subclass 7.1.

XXXI. Claims 53 – 56, 59, 60, 62, 64 – 65, and 67 – 68, drawn to a method of identifying a substance that regulates JTT-1 antigen function, comprising contacting a polypeptide comprising the extracellular domain of JTT-1 with a test substance, wherein the test substance is an antibody, classified in Class 435, subclass 7.1.

5. Groups I – VI are different products. The products are patentably distinct because their structures, physicochemical properties and/or mode of action are different, and they do not share a common structure that is disclosed to be essential for common utility. Furthermore, they require non-coextensive searches in the scientific literature. Therefore, each product is patentably distinct, and searching of these Inventions would impose an undue burden.

Groups VII – XXXI are different methods. The methods differ with respect to one or more of ingredients, method steps, and/or endpoints; therefore, each method is patentably distinct. Furthermore, some of these methods relate to different pathological conditions which are distinct because they differ in etiologies and therapeutic endpoints; thus each condition represents patentably distinct subject matter. The distinct ingredients, method steps, endpoints and/or pathological conditions require separate and distinct searches. As such, it would be burdensome to search these Inventions together.

Groups I – VI and VII – XXIV are related as product and process of using. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the compositions of Groups I – VI can be used for in vitro testing, in addition to the methods recited.

6. These inventions are distinct for the reasons given above. In addition, they have acquired a separate status in the art as shown by different classification and/or recognized divergent subject matter. Further, even though in some cases the classification is shared, a different field of search would be required based upon the structurally distinct products recited and the various methods of use comprising distinct method steps. Moreover, a prior art search also requires a literature search. It is an undue burden for the examiner to search more than one invention. Therefore restriction for examination purposes as indicated is proper.

### ***Species Election***

7. This application contains claims directed to the following patentably distinct Species of the claimed Inventions XIX – XXIV, wherein the inflammatory disease is one are selected from the group recited in claim 22.

These species are distinct because the pathological conditions differ in etiologies and therapeutic endpoints; thus each condition represents patentably distinct subject matter. Furthermore, the examination of species would require different searches in the scientific literature. As such, it would be burdensome to search these Species together.

Applicant is required under 35 USC 121 to elect a single disclosed species to which the claims would be restricted if no generic claim is finally held to be allowable.

8. Applicant is advised that a response to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.



Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 C.F.R. § 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. M.P.E.P. § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. § 103 of the other invention.

9. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. *Process claims that depend from or otherwise include all the limitations of the patentable product* will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is

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found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai*, *In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. *Failure to do so may result in a loss of the right to rejoinder.*

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

10. Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

11. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(h).

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12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to ILIA OUSPENSKI whose telephone number is 571-272-2920. The examiner can normally be reached on Monday-Friday 9 - 5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on 571-272-0841. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.


Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

ILIA OUSPENSKI, Ph.D.

Patent Examiner

Art Unit 1644

April 10, 2006

  
PHILLIP GAMBEL, PH.D. JD  
PRIMARY EXAMINER

R 1600  
4/10/06